Remarks

The various parts of the Office Action are discussed below under related headings.

Claim Rejection - 35 USC § 101

Claim 13 was rejected as being directed to non-statutory subject matter. This rejection is now moot in that claim 13 has been amended to recite subject matter that clearly is statutory.

Objection to Specification and Claim Rejection - 35 USC § 112, 1st ¶

The specification was objected to[1] and claims 7 and 9-14 were rejected for want of an enabling disclosure. According to the Examiner, the specific process for automatic data fusion and updating are not taught in the specification. Indeed, the specification does not describe at length such a process as the same was known in the art at the time the application was filed. Automatic image fusion programs existed and were available to persons skilled in the art at the time the application was filed. In view of this, it is respectfully submitted the application is enabling. Therefore, the objection to the specification and rejection of claims 7 and 9-14 should be withdrawn.

Claim Rejection - 35 USC § 112, 2nd ¶

The claims were rejected as being indefinite for several reasons. The Examiner's comments have been considered and the claims amended to remove any issue as to indefiniteness. Accordingly, the rejection should be withdrawn.

Claim Rejections - 35 USC § 103

The Examiner has rejected the claims as being unpatentable over Swerdloff U.S. Patent No. 5,661,773 taken alone or in combination with WO 97/40766. As will become apparent from the following discussion, the Swerdloff patent teaches a method that is fundamentally different from the claimed method.

As understood, Swerdloff somehow makes a treatment plan and then carries out that treatment. During the treatment, radiation errors are determined and then, based upon the determined errors, a next treatment is planned.

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[1] In the statement of the objection the Examiner referred to claim 1 but it appears that the Examiner int nded to refer to claim 7.

Applicants' method as set forth in the claims involv s producing or updating an inversely planned radiotherapy plan. The claimed m thod does not rely on the result of the actual treatment. Instead, applicants' method as claimed assumes the dose distribution has been set sufficiently good in the first inverse plan, and then calculates a new plan on the basis of the planned results of the first plan. The new up-to-date plan is adapted, for example, to new CT-data. Applicants' claimed method does not require a determination to be made of any errors that may have occurred during the earlier treatment.

That is, Swerdloff bases his second plan upon determined errors in the first plan while the applicants' method as claimed does not require determination of such errors but instead saves a lot of effort and time by reusing the planning data of the first plan instead of newly establishing another plan from scratch. The second plan is adapted from the first plan by taking into account, for example, organ shifts as determined by a new CT-scan. Swerdloff does not trust his original plan. Instead, it is assumed that errors will occur and Swerdloff seeks to correct these errors by building a completely new plan, which is exactly the effort the present invention avoids. In this regard, the Examiner's attention is directed to column 3, lines 57 to 61 of the Swerdloff patent, which reads:

> Where a treatment error (i.e. over or under radiation) has occurred, the error can be noted using the human interface and can be used to alter desired dose maps during later therapy sessions to compensate for the errors.

Also, in column 2, lines 51 to 63, it is said:

> After different irradiation zones within a tomographic image have been identified, the interface allows the operator to specify various radiation doses for each irradiation zone, to run a test simulation which takes into account radiation scatter during a therapy session to derive a theoretical pre-radiation dose map based on the doses specified by the operator, to easily change the doses specified by the operator as a function of the theoretical pre-radiation dose map that results, to verify radiation dose after a therapy session, and to plan for subsequent therapy sessions based on dose delivered during previous therapy sessions.

The last part, namely "to plan for subsequent therapy sessions based on dose delivered during previous therapy sessions," confirms that such technique is intended to take into account the actually applied dos (i.e. the rror therein) for future planning.

Moreover, dosage-volume histograms, the basis for the planning according to the present invention as claimed, are nowhere mentioned in the Swerdloff patent. For this additional reason, Swerdloff does not fairly teach or suggest applicants' invention as claimed.

WO 97/40766 does not overcome above-noted fundamental deficiencies of the Swerdloff reference as a teaching reference vis-a-vis the claimed subject matter. Thus, the applied references, taken alone or together, do not lead the skilled person to applicants' method as set forth in the claims.

As a final item, the Examiner, on the PTO-1449 form listing the art cited in the International Search Report, indicated consideration of four of the documents that were submitted. However, the Examiner drew a line through DE 199 12 708 for an unknown reason. The Examiner did write something in the margin, but it was partly cut off on the copy attached to the Office Action. The Examiner is requested to clarify why the German patent document was crossed off. It is noted that the relevance of the German patent document is indicated in the European Search Report, a duplicate copy of which is attached. In particular, the German patent document was cited as being of general background interest in respect of claims 4 and 7, with specific reference being made to column 3, lines 18-27, and column 4, lines 17-38.

This application is now believed to be in condition for allowance and an early action to that effect is earnestly solicited.

Respectfully submitted,

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A. Clean Version of Replacement Paragraph/Section/Claim with Instructions for Entry

Please amend the application as follows:

In the Claims:

Please substitute the following amended claims for those of the same number that are presently pending:

1. A method for producing or updating an inversely planned radiotherapy plan for fractionated radiation exposure of a patient, characterised in that an up-to-date radiotherapy plan is calculated at least partly on the basis of the results of an already existing, approved, older plan.

2. The method as set forth in claim 1, wherein pre-set values for calculating the inverse radiotherapy plan are determined from the results of a previously calculated plan.

3. The method as set forth in claim 1, wherein the patient is subject to an imaging method more than once over the duration of fractionated radiation exposure.

4. The method as set forth in claim 1, wherein the patient is subject to an imaging method before each radiotherapy session, wherein only a specified, defined area comprising the target volume is detected.

5. The method as set forth in claim 3, wherein the position of the patient relative to the imaging device is detected outside the region of the patient being imaged by the imaging device by the use of locating markers.

6. The method as set forth in claim 5, wherein the system for locating the markings is calibrated relative to the imaging device, such that the position of the markers can be determined relative to a data set recorded by the imaging device.

C2

10. The method as set forth in claim 9, wherein the information to be adopted into the new plan is transferred by means of a three-dimensional fusion of the contours, drawn in by hand, onto the layers or voxels of a new data set.

C3

12. The method as set forth in claim 9, wherein an image detection plane of an imaging device, with the aid of which the planning data set is to be updated, is determined in an image recording range by introducing a calibration phantom comprising markings which can be detected both by image detection and by an external tracking system, wherein a spatial relationship with the patient markings which are not detected by image detection is produced for the images detected.

13. A computer programmed to perform the method set forth in claim 1.

14. A computer program storage medium comprising a program which, when running on a computer, performs the method set forth in claim 1.

Please add the following new claim:

C4

15. The method as set forth in claim 3, wherein the imaging method is a CT or MR image recording method.

B. Version with Markings to Show Chang s Mad

Pl ase amend the application as follows:

In the Claims:

1. (Amended) A method for producing or updating [a] an inversely planned radiotherapy plan for fractionated radiation exposure of a patient [within the framework of inversely planned radiotherapy], characterised in that an up-to-date radiotherapy plan is calculated at least partly on the basis of the results of an already existing, approved, older plan.

2. (Amended) The method as set forth in claim 1, wherein [the] pre-set values for calculating the inverse radiotherapy plan are determined from the results of a previously calculated plan.

3. (Twice Amended) The method as set forth in claim 1, wherein the patient is subject to an imaging method [, preferably a CT or MR image recording method,] more than once over the duration of fractionated radiation exposure.

4. (Amended) The method as set forth in claim [3] 1, wherein the patient is subject to an imaging method before each radiotherapy session, wherein only a specified, defined area comprising the target volume is detected.

5. (Twice Amended) The method as set forth in claim [1] 3, wherein the position of the patient relative to the imaging device is detected outside the [recording range of] region of the patient being imaged by the imaging device [via] by the use of locating markers [, preferably infrared reflecting markers, by an imaging method, preferably a CT or MR image recording method, during or directly before or after recording a first patient data set].

6. (Amended) The method as set forth in claim 5, wherein the system for locating the markings is calibrated relative to the imaging [system] device, such that the position of the [markings] markers can be determined relative to [the recorded] a data set recorded by the imaging device.

7. The method as set forth in claim 1, wherein a data set comprising the target volume is supplem nted by automatic fusion with data from an older, larger volum data set, in order to obtain all the data necessary for calculating the dosage.

8. The method as set forth in claim 1, wherein th difference between the r sults of a new radiotherapy plan as compared to a previous plan are automatically quantified and, if the difference is within a previously specified tolerance range, the new plan is automatically qualified as an approved plan.

9. The method as set forth in claim 1, wherein, for transferring a radiotherapy plan onto a more recent planning data set, the position and form of a target volume and the organs to be protected are fully or partly adopted automatically into the new plan from the old plan.

10. (Amended) The method as set forth in claim 9, wherein the information to be adopted into the new [planning data set] plan is transferred by means of a three-dimensional fusion of the contours, drawn in by hand, onto the layers or voxels of [the] a new data set.

11. The method as set forth in claim 10, wherein fusion involves a graphic elastic morphing method of the information to be fused.

12. (Twice Amended) The method as set forth in claim 9, wherein an image detection plane of an imaging device, with the aid of which the planning data set is to be updated, is determined in [the] an image recording range by introducing a calibration phantom comprising markings which can be detected both by image detection and by an external tracking system, wherein a spatial relationship with the patient markings which are not detected by image detection is produced for the images detected.

13. (Twice Amended) A [program which, when running on a] computer [or loaded in a computer, causes the computer] programmed to perform the method [in accordance with] set forth in claim 1.

14. (Amended) A computer program storage medium comprising [the] a program [in accordance with claim 13] which, when running on a computer, performs the method set forth in claim 1.

New claims:

15. The method as set forth in claim 3, wherein the imaging method is a CT or MR image recording method.